REMARKS

Comments on Finality of Previous Office action

Applicants requested in their previous Reply that the Finality of the Office action mailed March 11, 2009, be withdrawn. In that action, the basis of the 35 U.S.C. § 102 rejection was rewritten to include reliance on the O'Byrne (Am.J.Respir.Crit.Care 1999) article. That Office action clearly modified the previously existing rejection to add reliance on the alleged teachings in the O'Byrne article. The comments in that Office action in support of the 35 U.S.C. §102 rejection rely almost totally on O'Byrne. This was clearly a new ground of rejection. The new ground of rejection was not necessitated by any claim **amendments** made by applicants. This should have been evident because applicants did not make any amendments in their Reply previous to this Final action. The Advisory action indicates that it was proper to make the new rejection final because applicants provided new rebuttal arguments against the other references. But new **arguments** by applicants which necessitate a new rejection do not warrant such a rejection being made Final. MPEP §706.07(a), quoted below, makes very clear that the new rejection must be necessitated by claim **amendments**, not merely **arguments**, to be properly made final:

> Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement.

Applicants filing of the RCE here does not render this point moot because the previous improper practice should necessitate that an Office action in response to this reply should not be made Final even if the same rejection is applied. Applicants have still not been provided an opportunity to have full consideration of their arguments against the new ground of rejection without being subject to the constraints of a Final action status. Thus, applicants urge that the next Office action cannot be made Final.

The Rejection under 35 U.S.C. §102

The rejection of claims 9, 11-15, 31 and 32 under 35 U.S.C. §102, as being anticipated by Maesen (Eur.Respir.J.) in view of O'Byrne (Am.J.Respir.Crit.Care 1999), is respectfully traversed.

The added reliance on the O'Byrne article does not make up for the previously noted deficiencies of Maesen and does not otherwise support the rejection. The O'Byrne article

(like Maesen) fails to mention anything regarding treating "cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis." O'Byrne and Maesen fail to provide valid support for the allegation in the Office action that "treatment of the symptoms of COPD would inherently treat cystic fibrosis, emphysema or fibrosing alveolitis." The Advisory action states that O'Byrne is used to "show that COPD encompasses cystic fibrosis," citing page S47. However, O'Byrne never mentions the term "cystic fibrosis" at this page or elsewhere. O'Byrne does indicate that "fibrosis" of an unspecified nature can be an ultimate symptom of COPD, but there is no mention specifically of "cystic fibrosis." Further, even if O'Byrne did relate specifically to "cystic fibrosis" it does not teach that COPD "encompasses" cystic fibrosis only that it can ultimately be a symptom. As for the teachings in O'Byrne regarding emphysema mentioned in the Final action, the claims are not directed to treating emphysema.

Maesen teaches that tiotropium bromide can be used to treat COPD. Maesen does not teach that tiotropium bromide can be used to treat any specific symptom of COPD – whether associated with COPD or not. The statement in the Advisory action that: "Since COPD encompasses the cystic fibrosis, it would inherently treat cystic fibrosis," does not have any supporting basis in the cited references. Nor is it clear what is meant by the allegation that one disease "encompasses" another disease. There is no basis on the record to support that all COPD patients have cystic fibrosis or vice versa. The prior art merely teaches that COPD can lead to some manner of fibrosis, not necessarily cystic fibrosis. It does not follow logically that a teaching in a reference that a compound can be used to treat a disease (i.e., COPD) also teaches that the compound can be used separately to treat any symptom that might appear with the disease. Although the facts are reversed in Rapoport v. Dement, 254 F.3d 1053, 59 USPQ2d 1215 (Fed. Cir. 2001) – finding that treating one possible symptom does not amount to a teaching to treat the underlying disease or condition – the reasoning is analogously applicable. There is no reasonable expectation to one of ordinary skill in the art that a compound useful for treating a disease or condition would also be useful for treating a condition that may be a symptom of the underlying disease or condition, even when not associated with the underlying disease or condition.

In any event, Maesen and O'Byrne fail to even support that any of cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis, specifically, are symptoms of COPD. As pointed out above, neither of the references include mention any of these specific terms.

O'Byrne does appear to support that fibrosis of an unspecified nature can ultimately occur from COPD. But O'Byrne does not specifically refer to cystic fibrosis, idiopathic lung

fibrosis or fibrosing alveolitis. Further, O'Byrne does not support that any particular fibrosis necessarily and inevitably occurs with COPD. Thus, even if it did have specific teachings, it would lack teaching necessary for an inherency argument. For an inherency rejection, the patent law requires that the alleged inherent phenomena necessarily and inevitably occurs, as opposed to a phenomena which might occur, from a given set of conditions; see, e.g., In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); and In re Oelrich, 212 USPQ 323, 326 (CCPA 1981). O'Byrne does not teach that fibrosis (let alone a specific kind) necessarily and inevitably occurs with COPD.

In any event, even if the references supported that cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis is a necessary and inevitable symptom of COPD, such a fact would still not support that a method for treating COPD would necessarily treat one of these particular symptoms.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §102 should be withdrawn.

The Rejection under 35 U.S.C. §103

The rejection of claims 9, 11-23 and 25-32 under 35 U.S.C. §103, as being obvious over Maesen, as applied above, further in view of Skupin (U.S. Patent No. 5,250,286) and Hochrainer (U.S. Patent No. 6,150,418) (optionally also taking O'Byrne (Am.J.Respir.Crit.Care 1999) in consideration), is respectfully traversed.

The discussion of Maesen and O'Byrne and of the combined teachings of Maesen and O'Byrne from above are incorporated herein by reference. To summarize, neither of Maesen or O'Byrne provide any specific mention of cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis – let alone a method for treating these conditions.

The Skupin and Hochrainer references were previously relied upon for their teachings regarding the use of certain excipients in connection with active agents administered by inhalation. Applicants maintain their position that carrying out the method of Maesen (with or without the excipients taught in Skupin and/or Hochrainer) will not produce or suggest the claimed invention. As detailed above, Maesen teaches only a method for treating COPD and fails to teach or suggest a "method for treating an inflammatory component of a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis." As further detailed above, O'Byrne does not suggest that the method of Maesen for treating COPD will also treat cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis. Since none of the

cited references teaches or suggests a method for treating a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis, the combination of references cannot teach or suggest this element of the claimed invention.

The Advisory action further alleges that Skupin teaches a method for "treatment of the symptoms of COPD, which includes such entitities as cystic fibrosis, chronic bronchitis, emphysema, and COPD where it is associated with asthma." However, Skupin does not provide any suggestion that a tiotropium salt can be used to achieve such a method. Skupin relates to the combination of completely unrelated imidazoline and alpha-adrenergic blocking agent compounds for its method. No explanation is provided to support why Skupin's teachings would suggest to one of ordinary skill in the art that a tiotropium salt could be used to achieve the Skupin method. The compounds taught for the Skupin method are structurally unrelated to tiotropium salts. As the Advisory action further states, Skupin is relied on only for its teachings regarding the use of certain excipients.

Additionally, applicants maintain that no valid reason is established for combining the reference teachings in the manner suggested in the Office action. In response, the Office action points to the basic legal tenet that the motivation for combining the references can be found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. But stating the legal principal is not a substitute for actually providing an articulated reason why one of ordinary skill in the art would combine the reference teachings in the manner suggested to support the rejection. The Office action merely states what portions of the individual references teaching are relied on. But no reason for why they would be combined is provided. See, KSR International Co. v. Teleflex Inc., 550 U.S. _, 82 USPQ2d 1385, at 1396 (2007), where the Supreme Court stated: "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

Skupin teaches the use of certain excipients in connection with particular alpha-adrenergic blocking agents. Hochrainer teaches the use of certain excipients in connection with the particular beta-2-stimulator formoterol. Neither of the references provide any reason for one of ordinary skill in the art to reasonably expect that the excipients taught therein would also be useful in combination with a tiotropium salt anticholinergic. The active compounds used in Skupin and Hochrainer are completely distinct from tiotropium both in structure and activity.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §103 should

be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/John A. Sopp/

John A. Sopp, Reg. No. 33,103
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: 01-1196-1-C1

Date: November 2, 2009

JAS:dap